K063619
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510(k) SUMMARY

Submitted By: Lisa Webb, MBA, RAC
Regulatory Affairs Manager
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2643
December 4, 2006

DEC 20 2006

Device:

Trade Name:	Flipper® Detachable Embolization Coil (Inconel)
Proposed Classification Name:	Device, Vascular, Embolization 21 CFR 870.3300, KRD
Indications for Use:	Used for arterial and venous embolization in the peripheral vasculature.

Predicate Devices:

The Flipper® Detachable Embolization Coil (Inconel) is similar in terms of intended use, materials of construction, and technological characteristics to the predicate Flipper® Detachable Embolization Coil (stainless steel) and MReye® Embolization Coil.

Device Description:

The Flipper® Detachable Embolization Coil (Inconel) is used for arterial and venous embolization procedures in the peripheral vasculature. The device is supplied sterile and intended for one-time use. The embolization coil is pre-loaded in a shipping cannula. The coil is constructed of Inconel and has a coil wire diameter of 0.035 inches. It is available in a curled shape. The emboli size range is 3 to 8 mm. The embolization coil includes synthetic fibers evenly placed down the length of the coil. The device is introduced to the target vessel using an angiographic catheter (sold separately) and deployment is achieved when the threads between the coil and the Flipper® Detachable Coil Delivery Wire are unscrewed.

Substantial Equivalence:

Cook Incorporated currently markets the Flipper® Detachable Embolization Coil (stainless steel—K993455) and the MReye® Embolization Coil (K052834), to which the Flipper® Detachable Embolization Coil (Inconel) is substantially equivalent. The similar indications for use, materials of construction, and technological characteristics of the Flipper® Detachable Embolization Coil (Inconel) as compared to the predicate devices support a determination of substantial equivalence.

Test Data:

Testing data are presented to demonstrate that the Flipper® Detachable Embolization Coil (Inconel) meets applicable design and performance requirements.

- Coil Deformation Testing
- Wire Tensile Strength
- Delivery Friction Testing
- Fiber Pull-Out Testing
- Detachment Reliability Testing
- Magnetic Resonance (MR) Testing

The results of these tests provide reasonable assurance that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2006

Cook, Incorporated
c/o Lisa Webb, MBA, RAC
Regulatory Affairs Manager
P.O. Box 489
Bloomington, IN 47402-0489

Re: K063619
Trade/Device Name: Flipper® Detachable Embolization Coil
Regulation Number: 21 CFR 870.3300
Regulation Name: Embolectomy Coil
Regulatory Class: II (two)
Product Code: KRD
Dated: December 4, 2006
Received: December 5, 2006

Dear Ms. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

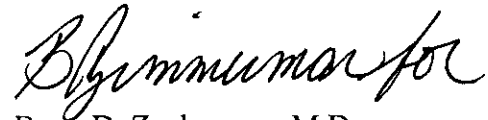
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063619

Device Name: Flipper® Detachable Embolization Coil (Inconel)

Indications for Use: Used for arterial and venous embolization in the peripheral vasculature.

Prescription Use XX OR Over-the-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063619